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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,063	08/27/2001	Michael J. Briskin	1855.1070-004	3846

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EXAMINER	
LOCKARD, JON MCCLELLAND	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/940,063	BRISKIN ET AL.	
	Examiner	Art Unit	
	Jon M Lockard	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,21-47,53,60,84,88,97-109 and 111-121* is/are pending in the application.

4a) Of the above claim(s) *16,47,53,60 and 115* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-46,53,84,88,97-109,111-114 and 116-121* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *25 Aug 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1647, Examiner Jon Lockard.

2. The amendment and response filed 22 March 2004 has been received and entered in full. Claim 110 has been cancelled, Claims 16, 21, 27, 34, 41, 47, 53, 60, 84, 103, and 115 have been amended, and Claims 116-121 have been added.

3. Applicant's request for rejoinder of claims 16, 47, 53, 60, and 115 in accordance with MPEP §821.04 is acknowledged. However, in view of the rejection set forth with respect to product claim 21, rejoinder is held in abeyance.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

5. Applicant's Supplemental IDS, filed 25 August 2003, is acknowledged.

Withdrawn Objections And/Or Rejections

6. The Declaration filed on 22 March 2004 under 37 CFR 1.131 is sufficient to overcome the Catalog #MAB699 (IDS # AY4) and MacPhee et al. (WO 99/50670, IDS #AL) references. Therefore:

7. The rejection of claims 21-27, 34-46, and 103-114 under 35 U.S.C. §102(a) as being anticipated by Catalog #MAB699 (IDS #AY4) as set forth at page 6 ¶18 of the previous Office Action (mailed 22 September 2003) is withdrawn;

8. The rejection of claims 21-22, 24-27, 34-38, 40-45, 97-102, and 109-114 under 35 U.S.C. §102(a) as being anticipated by MacPhee et al. (WO 99/50670, IDS #AL) as set forth at page 7 ¶19 of the previous Office Action (mailed 22 September 2003) is withdrawn;

9. The rejection of claims 84 and 88 under 35 U.S.C. §103(a) as being unpatentable over Catalog #MAB699 (IDS #AY4) in view of Jardieu et al. (US Pat. No. 6,037,454) as set forth at page 8 ¶22 of the previous Office Action (mailed 22 September 2003) is withdrawn, and;

10. The rejection of claim 84 under 35 U.S.C. §103(a) as being unpatentable over MacPhee et al. (WO 99/50670, IDS #AL) as set forth at page 9 ¶23 of the previous Office Action (mailed 22 September 2003) is withdrawn.

11. The provisional rejection of claims 21 and 34 under 35 U.S.C. § 101 as claiming the same invention as that of claims 21 and 34 of copending U.S. Application No. 10/1`74,293 as set forth at pages 22-23 of the previous Office Action (mailed 22 September 2003) is withdrawn in view of the amended claims which now recite "mammalian ligand".

12. Applicant's arguments, see pages 15-17, filed 22 September 2003, with respect to the rejection(s)of claim(s) 23, 39, and 46 under 35 U.S.C. §112¶2 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Applicant's disclosure that mammalian SExCkine refers to naturally-occurring or endogenous mammalian SExCkine proteins, as well as

"polymorphic or allelic variants, and other isoforms of a mammalian SExCkine produced by alternative splicing, proteolytic processing or other cellular processes" (See page 16).

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 23, 39, and 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

15. Claims 23, 39, and 46 are directed to a genus of ligands that is given the name SExCkine.

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶1 "Written Description" Requirements make clear that the written description requirement for a claimed genus may be satisfied by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

16. However, there does not appear to be an adequate written description in the specification as-filed of any essential structural feature, structure/function correlation, or biological activity

common to molecules defined by Applicant's as SExCkine. The distinguishing characteristics of the claimed genus are not described. The only adequately described species of SExCkine are the proteins set forth as SEQ ID NO:4 and SEQ ID NO:6. Accordingly, the specification does not provide adequate written description of the claimed genus.

17. The objection to claim 110 as set forth at page 3 ¶9 of the Previous Office Action (mailed 22 September 2003) is moot in view of Applicant's cancellation of said claim (filed 22 March 2004).

18. The rejection of claim 110 under 35 U.S.C. §112¶1 and 35 U.S.C. §102(a) as set forth at pages 4-7 ¶15-19 of the previous Office Action (mailed 22 September 2003) is moot in view of Applicant's cancellation of said claim (filed 22 March 2004).

Maintained Objections And/Or Rejections

19. Claims 21-22, 24-27, 34-38, 40-45, 84, 88, 97-109, 111-114, and newly submitted claims 116-121 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth at page 4 ¶15 of the previous Office Action (22 September 2003).

20. Applicant's traverse this rejection on the following grounds: **(a)** claims 21, 31, 34, 41, and 84 have been amended to recite "mammalian ligand", **(b)** newly added claims (116-121) which recite "chemokine ligand", and **(c)** applicant's disclose nucleic acid and amino acid

sequences for several mammalian ligands that bind Bonzo including, e.g., human SExCkine (SEQ ID NOs: 3 and 4), human chemokine alpha-5 (SEQ ID NOs:5 and 6), and human platelet factor-4 (SEQ ID NOs: 7 and 8). Applicant's arguments have been fully considered but are not found persuasive for the following reasons.

21. Applicant's argument is persuasive to the extent that the specific ligands disclosed are adequately described. However, even though applicant's have narrowed the claims to recite "mammalian ligand" or "chemokine ligand", applicant's have only described 2 species (SExCkine and PF4) of ligands that bind Bonzo. The genus of molecules encompassed by the term "mammalian ligand" or "chemokine ligand" is very large and highly diverse, and includes any molecule which has the function of binding Bonzo. Thus, the disclosure of two species of ligands does not appear to provide an adequate written description of the extensive genus of molecules which are "mammalian or chemokine ligands that bind Bonzo". Furthermore, without an adequate written description of the "mammalian or chemokine ligands that bind Bonzo", one cannot adequately describe an antibody that inhibits the binding of said ligands to Bonzo.

22. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Claims 97-102 and newly submitted claims 116-121 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

24. Claims 97-102 are rejected as being indefinite because without knowing what ligand and what in vitro assay, the metes and bounds of the claims cannot be determined.

25. Claims 116-121 are rejected as being indefinite because it is unclear of the meaning of the term "chemokine ligand". Without knowing whether "chemokine ligand" is a chemokine that binds Bonzo or refers to something completely different, the metes and bounds of the claims cannot be determined.

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

27. Claims 21-26, 34-46, 97-102, 109, 113-114, and 116-121 are rejected under 35 U.S.C. 102(b) as being anticipated by Farber et al. (WO 98/44098, IDS #AP, see entire document).

28. Farber et al. teach that the human STRL33 protein is bound by HIV as part of the entry of HIV into cells (see entire document, e.g., "Summary of the Invention" on pages 3-5). Thus HIV is a ligand of human STRL33. STRL33 is human Bonzo, as shown by the amino acid sequence presented in Figure 4. Farber et al. also teach antibodies and antibody fragments which bind STRL33 and block membrane fusion between HIV and a target cell (see page 4 at lines 5-7 and pages 26-33). Farber et al. also teach the cell lines, including hybridomas, which produce these antibodies (e.g., page 29).

29. Farber et al. are silent as to the functional properties of the monoclonal antibody to human Bonzo.

30. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. Since the antibody taught by Farber et al. binds human Bonzo, and this binding blocks membrane fusion between HIV (ligand) and Bonzo, the instantly recited

properties of inhibition of mammalian ligand, SExCkine binding, inhibition of signal transduction and/or the various cellular responses recited would be inherent properties of the antibody taught by Farber et al. Further, an antibody that would inhibit binding of HIV to Bonzo would inherently be inhibited to at least some degree by the binding of one or more of the deposited antibodies 4A11, 7A2, or 7F3.

31. Although the reference does not appear to teach what minimum IC_{50} values the antibodies should have, a variety of assays and conditions (wherein IC_{50} values are determined) are encompassed by the claim language, and therefore the limitation has not been given patentable weight.

32. Applicant's traverse this rejection by amending independent claims 21 and 34 to recite "mammalian ligand" and newly added claims which recite "chemokine ligand".

33. However, since HIV is mammalian in origin and only replicates in mammalian cells, the Examiner considers HIV to be a mammalian ligand. Furthermore, as discussed above, an antibody that inhibits binding of HIV to Bonzo would, in the absence of evidence to the contrary, inhibit binding of any other ligand to Bonzo.

34. Applicant is reminded that "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on 'prima facie obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980)

(quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). See MPEP 2112.

35. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

36. Claims 84 and 121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farber et al. in view of Jardieu et al. (U.S. Pat. No. 6,037,454).

37. The claim is drawn to a test kit for detecting the presence of Bonzo in a biological sample comprising an antibody which binds Bonzo and inhibits binding of a mammalian ligand, and one or more ancillary reagents suitable for detecting the antibody-Bonzo complex.

38. The teachings of Farber et al. have been discussed in detail supra.

39. Farber et al. do not teach an antibody to Bonzo in a test kit comprising one or more ancillary reagents suitable for detecting the antibody-Bonzo complex.

40. However, the formulation of antibodies that detect receptors expressed on the surface of a cell into a kit comprising ancillary reagents for the detection of the antibody-receptor complex would have been obvious to the ordinary artisan at the time the invention was made in view of any teaching of the antibody.

41. For example, Jardieu et al. teach antibodies to another cell surface receptor, CD11A (see entire document). Jardieu et al. teach that antibodies can be used in numerous diagnostic assays

to detect proteins, and that many different agents are available for detecting the antibody bound to its antigen (see e.g., columns 28-30). Jardieu et al. also teach that as a matter of convenience, antibodies and ancillary agents for detecting the binding of the antibody to the target antigen may be packaged together in a kit (see column 30, especially lines 19-34).

42. It would have therefore have been obvious to one of ordinary skill in the art at the tie the invention was made to combine the anti-Bonzo antibody of Farber et al. with one or more ancillary reagents for detecting the antibody-Bonzo complex. The ordinary artisan at the time the invention was made would have been motivated to provide the antibody in a kit as a matter of convenience, as taught by Jardieu et al. Given the teaching of Farber et al. of the anti-Bonzo antibody, and the teachings of Jardieu et al. regarding the numerous ancillary reagents available, the ordinary artisan would have had a reasonable expectation of formulating the antibody in a kit with one or more ancillary reagents.

43. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

44. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

45. Claims 21-46, 84, 88, and 97-114 are provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 21, 28, 31, 34, 197-201, 203, and 205-206 of copending Application No. 10/174,293 for reasons of record set forth in the previous Office Action (mailed 22 September 2003).

46. Applicant's intention to resolve the issue is noted.

Summary

47. No claim is allowed

Allowable Subject Matter

48. Claims 27, 88, 103-108, 111-112 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

the base claim and any intervening claims, and the conflicting claims in USSN 10/174,293 were cancelled.

49. Claims 27-33 would appear to be allowable if the conflicting claims in USSN 10/174,293 were cancelled as the prior art does not teach or suggest the particular species of antibodies and cell lines producing said antibodies.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML
July 22, 2004

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER